Amir M. Nassihi (SBN: 235936)
anassihi@shb.com
SHOOK, HARDY & BACON L.L.P.
555 Mission Street Suite 2300
San Francisco, California 94105
Telephone: (415) 544-1900
Facsimile: (415) 391-0281

Michael L. Mallow (SBN: 188745)
mmallow@shb.com
Mayela C. Montenegro-Urch (SBN: 304471)
mmontenegro@shb.com
SHOOK, HARDY & BACON L.L.P.
2049 Century Park East, Suite 3000
Los Angeles, California 90067
Telephone: (424) 285-8330
Facsimile: (424) 204-9093

[Additional Counsel on Signature Page]

Attorneys for Defendants
INTERNATIONAL MEDICAL DEVICES, INC., MENOVA INTERNATIONAL, INC., GESIVA MEDICAL, LLC, JAMES J. ELIST, M.D., A MEDICAL CORPORATION, and DR. JAMES ELIST
Attorneys for Defendants
INTERNATIONAL

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA – EASTERN DIVISION

EDWARD PENA, individually and on behalf of others similarly situated,

Plaintiff,

v.

INTERNATIONAL MEDICAL DEVICES, INC., MENOVA INTERNATIONAL, INC., GESIVA MEDICAL, LLC, JAMES J. ELIST M. D., a Medical Corporation, and Dr. James ELIST

Defendants.

Case No. 2:22-cv-03391-SSS (PLAx)

Judge: Hon. Sunshine S. Sykes

DEFENDANTS' NOTICE OF MOTION AND MOTION TO DISMISS FIRST AMENDED CLASS ACTION COMPLAINT; MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT THEREOF

[Filed concurrently with Request for Judicial Notice and [Proposed] Order]

Date: October 14, 2022
Time: 2:00 p.m.
Ctrm: 2 (via Zoom video conference)

Complaint Filed: May 25, 2022
First Am. Compl. Filed: June 15, 2022

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that on October 14, 2022, at 2:00 p.m., or as soon thereafter as this matter may be heard before the Honorable Sunshine S. Sykes via Zoom video conference in Courtroom 2 of the United States Courthouse located at 3470 Twelfth Street, Riverside, California 92501, Defendants International Medical Devices, Inc., Menova International, Inc., Gesiva Medical, LLC, James. J. Elist M.D., A Medical Corporation, and Dr. James Elist (collectively, "Defendants") will move the Court for an order dismissing Plaintiff Edward Peña's First Amended Complaint ("FAC"). This motion is made pursuant to Rules 8(a), 9(b), and 12(b)(6) of the Federal Rules of Civil Procedure.

Peña's FAC should be dismissed in its entirety for the following reasons:

First, Peña does not identify the specific advertisements he read, when he read them, or how they misled him, as he must for fraud-based claims subject to Rule 9(b). Peña also improperly lumps all of the Defendants together without differentiating the allegations against each Defendant, as Rules 8 and 9(b) require.

Second, even if Peña had properly identified the advertisements he saw and relied upon, he has not pleaded any actionable misrepresentation or omission. The website screenshots in the complaint omit most of the information on those webpages, which, when read as a whole, are not likely to mislead a reasonable consumer as a matter of law. To the extent Peña alleges any omissions, they also are not actionable because he has not alleged the circumstances creating a duty to disclose.

Third, the UCL unlawful and unfair practices claims fail because Peña has not alleged a separate basis for those claims beyond the non-actionable advertisements.

Fourth, the claims against International Medical Devices, Inc. ("IMD"), Gesiva Medical, LLC ("Gesiva"), and Menova International, Inc. ("Menova") fail for additional reasons.

Fifth, Peña fails to allege facts showing entitlement to equitable relief.

This motion is based on this notice of motion and motion, the accompanying memorandum of points and authorities, the accompanying request for judicial notice, the pleadings and documents on file in this action, and such other evidence and argument as may be presented at or before the hearing on this motion.

This motion is made following the conference of counsel pursuant to L.R. 7-3, which took place on July 22, 2022.

Dated: August 1, 2022

Respectfully submitted,

SHOOK, HARDY & BACON L.L.P.

By: /s/ *Amir M. Nassihi*
Amir M. Nassihi
Michael L. Mallow
Jennifer M. Stevenson
Mayela C. Montenegro-Urch

Jennifer M. Stevenson (admitted *pro hac vice*)
jstevenson@shb.com
SHOOK, HARDY & BACON L.L.P.
2555 Grand Boulevard
Kansas City, Missouri 64108
Telephone: (816) 474-6550
Facsimile: (816) 421-5547

Attorneys for Defendants
INTERNATIONAL MEDICAL DEVICES, INC., MENOVA INTERNATIONAL, INC., GESIVA MEDICAL, LLC, JAMES J. ELIST M.D., a Medical Corporation, and DR. JAMES ELIST

TABLE OF CONTENTS

INTRODUCTION 1
FACTUAL BACKGROUND 2
A. History of the Penuma implant 2
B. Peña's experience with the Penuma implant 4
C. Peña's allegations regarding Penuma advertising 5
LEGAL STANDARD 9
ARGUMENT 10
I. Peña has not stated a claim for violation of the consumer-protection statutes. 10
A. The FAC fails to plead with particularity as Rule 9(b) requires 11
B. Peña has failed to plead an actionable misrepresentation. 12
C. Peña has failed to plead an actionable omission. 19
D. Peña fails to allege any "unlawful" or "unfair" practices under the UCL. 20
II. Peña's claims against IMD and Gesiva fail for additional reasons 21
III. Peña's claims against Menova fail for additional reasons. 22
IV. The Court should dismiss Peña's claims for equitable relief. 23
CONCLUSION 25

TABLE OF AUTHORITIES

Cases **Page(s)**

Adams v. Cole Haan, LLC,
2020 WL 5648605 (C.D. Cal. Sept. 3, 2020) 22

Andren v. Alere, Inc.,
207 F. Supp. 3d 1133 (S.D. Cal. 2016) 19, 21

Aranda v. County of Los Angeles,
2020 WL 913422 (C.D. Cal. Feb. 6, 2020) 11

Ashcroft v. Iqbal,
556 U.S. 662 (2009) 9

Bates v. United Parcel Serv., Inc.,
511 F.3d 974 (9th Cir. 2007) 23

Bell Atl. Corp. v. Twombly,
550 U.S. 544 (2007) 9, 16

Chapman v. Pier 1 Imports (U.S) Inc.,
631 F.3d 939 (9th Cir. 2011) 23

Chong v. Nestlé Waters N. Am., Inc.,
2020 WL 7690175 (C.D. Cal. Nov. 30, 2020) 10, 20

Clark v. Am. Honda Motor Co.,
528 F. Supp. 3d 1108 (C.D. Cal. 2021) 22

Destfino v. Reiswig,
630 F.3d 952 (9th Cir. 2011) 11

Drake v. Toyota Motor Co.,
2020 WL 7040125 (C.D. Cal. Nov. 23, 2020) 11, 23

Ebner v. Fresh, Inc.,
838 F.3d 958 (9th Cir. 2016) 10

Franckowiak v. Scenario Cockram USA, Inc.,
2020 WL 9071697 (C.D. Cal. Nov. 30, 2020) 23

Gibson v. Jaguar Land Rover N. Am., LLC,
2020 WL 5492990 (C.D. Cal. Sept. 9, 2020) 22

Goldstein v. Gen. Motors LLC,
517 F. Supp. 3d 1076 (S.D. Cal. 2021) 23

Gutierrez v. Johnson & Johnson Consumer Inc.,
2021 WL 822721 (S.D. Cal. Jan. 22, 2021) 10

Herrara v. Estee Lauder Cos.,
2012 WL 12507876 (C.D. Cal. Sept. 20, 2012) 10

Hodsdon v. Mars, Inc.,
891 F.3d 857 (9th Cir. 2018) 18

Holt v. Noble House Hotels & Resort, Ltd.,
370 F. Supp. 3d 1158 (S.D. Cal. 2019) 13, 14

Jackson v. East Bay Hosp.,
246 F.3d 1248 (9th Cir. 2001) 11

Janney v. Gen. Mills,
944 F. Supp. 2d 806 (N.D. Cal. 2013) 10

Jones v. Smithkline Beecham Corp.,
2008 WL 11340340 (C.D. Cal. Aug. 19, 2008) 21

Kearns v. Ford Motor Co.,
567 F.3d 1120 (9th Cir. 2009) 9, 10

Klaehn v. Cali Bamboo LLC,
2022 WL 1830685 (9th Cir. June 3, 2022) 22

Knuttel v. Omaze, Inc.,
2022 WL 1843138 (C.D. Cal. Feb. 22, 2022) 20

Lanovaz v. Twinings N. Am., Inc.,
726 F. App'x 590 (9th Cir. 2018) 24

LiMandri v. Judkins,
52 Cal. App. 4th 326 (1997) 18

Loo v. Toyota Motor Sales, USA, Inc.,
2020 WL 4187918 (C.D. Cal. Apr. 10, 2020) 23

Madrigal v. Hint, Inc.,
2017 WL 6940534 (C.D. Cal. Dec. 14, 2017) 22

Maher v. Novartis Pharms. Corp.,
2007 WL 2330713 (S.D. Cal. Aug. 13, 2007) 21

Morris v. Sun Pharma Global Inc.,
2021 WL 3913191 (C.D. Cal. May 13, 2021) 11

Motus v. Pfizer, Inc.,
196 F. Supp. 2d 984 (C.D. Cal. 2001), *aff'd*, 358 F.3d 659 (9th Cir. 2004) 21

Naimi v. Starbucks Corp.,
2018 WL 11255596 (C.D. Cal. Feb. 28, 2018) 12, 14

Patt v. Antech Diagnostics, Inc.,
2020 WL 5076970 (C.D. Cal. May 18, 2020) 19

PDF Print Commc'ns Inc. v. Federated Mut. Ins. Co.,
2022 WL 2189631 (C.D. Cal. Mar. 29, 2022) 22

Plenger v. Alza Corp.,
11 Cal. App. 4th 349 (1992) 21

Rahman v. Mott's LLP,
2018 WL 4585024 (N.D. Cal. Sept. 25, 2018) 24

Ratha v. Phatthana Seafood Co.,
35 F.4th 1159 (9th Cir. 2022) 11

Repro-Med Sys., Inc. v. EMED Techs. Corp.,
2019 WL 1427978 (E.D. Cal. Mar. 29, 2019) 16

Rodriguez v. Just Brands USA, Inc.,
2021 WL 1985031 (C.D. Cal. May 18, 2021) 23, 24

Saavedra v. Eli Lilly and Co.,
2013 WL 3148923 (C.D. Cal. June 13, 2013) 21

Sciacca v. Apple, Inc.,
362 F. Supp. 3d 787 (N.D. Cal. 2019) 24

Shapiro v. AT&T Mobility, LLC,
2021 WL 4798726 (C.D. Cal. July 28, 2021) 19

Sonner v. Premier Nutrition Corp.,
971 F.3d 834 (9th Cir. 2020) 22, 23

Summers v. Earth Island Inst.,
555 U.S. 488 (2009) 24

Thornton v. Micro-Star Int'l Co.,
2017 WL 10621210 (C.D. Cal. Aug. 21, 2017) 11

Williams v. Gerber Prods. Co.,
552 F.3d 934 (9th Cir. 2008) 10

Wolph v. Acer Am. Corp.,
2009 WL 2969467 (N.D. Cal. Sept. 14, 2009) 19

Statutes

21 U.S.C. § 360c(a)(1)(C) 3

Consumers Legal Remedies Act, Cal. Civ. Code § 1750 ..... 8, 9, 10, 20, 21

Cal. Bus. & Prof. Code § 17500 ..... 8, 9, 10, 20, 21

Food, Drug, and Cosmetic Act section 510(k) 2, 10, 20

Sherman Food, Drug, and Cosmetic Law 10, 20

Unfair Competition Law, Cal. Bus. & Prof. Code § 17200 8

Rules

Fed. R. Civ. P. 8 ..... 1, 9, 11

Fed. R. Civ. P. 9 ..... 1, 9, 10, 11

Other Authorities

21 C.F.R. § 807.92 2

21 C.F.R. § 807.100 ..... 2, 3, 4, 5

INTRODUCTION

Edward Peña alleges he underwent outpatient surgery in October 2020 for implantation of the Penuma® penile implant ("Penuma"). According to Peña, he did so after initially seeing internet advertisements and believing the implant would enlarge the size of his penis and the procedure was safe, effective, and could be reversed, if necessary, without any adverse effects from removal. Peña alleges he experienced some complications post-surgery and is among the small percentage of men who have had the implant removed. But Peña is not bringing a product liability or medical malpractice action as one might expect if there was something actually wrong with the implant or the surgery. Rather, he alleges that Defendants—and chiefly, Dr. James Elist ("Dr. Elist"), the urologist who invented the Penuma and performed his surgery—misrepresented the Penuma's safety and effectiveness on their websites and, as a result, misled him (and others) into paying for an implant and procedure that he considers worthless based on his unique personal experience. Among other things, Peña seeks to recover money he and anyone else in the United States paid for the Penuma implantation surgery performed by Dr. Elist over the past four years.

The Court should dismiss the FAC in its entirety for several reasons.

First, Peña does not identify the specific advertisements he read, when he read them, or how they misled him, as he must for fraud-based claims subject to Rule 9(b). Peña also improperly lumps all of the Defendants together without differentiating the allegations against each Defendant, as Rules 8 and 9(b) require. These pleading failures alone require dismissal of all his claims.

Second, even if Peña had properly identified the advertisements he saw and relied upon, he has not pleaded any actionable misrepresentation or omission. The website screenshots in the complaint omit most of the information on those webpages, which, when read as a whole, are not likely to mislead a reasonable consumer as a matter of law. For example, while the screenshots state that the implant is designed to

enlarge penis size, the webpages also state numerous times that increases in size are *possible*, not guaranteed, and individual results can vary. Similarly, these webpages identify a number of potential complications from the procedure, including the potential need for removal. Most importantly, the websites repeatedly state that before undergoing the procedure patients will have to go through a screening process followed by pre-operative counseling, and that all of the possible benefits, risks, complications, and alternatives, including no surgery, will be discussed in advance of the surgery. Peña does not and cannot allege that this discussion failed to occur (indeed, he signed a detailed consent form showing that it did). To the extent Peña alleges any omissions, they also are not actionable because he has not alleged the circumstances creating a duty to disclose.

Third, the UCL unlawful and unfair practices claims fail because Peña has not alleged a separate basis for those claims beyond the non-actionable advertisements.

Fourth, the claims against IMD, Gesiva, and Menova fail for additional reasons.

Finally, Peña fails to allege facts showing entitlement to equitable relief.

Accordingly, the Court should grant the motion to dismiss.

FACTUAL BACKGROUND

A. History of the Penuma implant

In 2004, National Medical Devices, Inc., the predecessor to IMD, applied for and received clearance from the U.S. Food and Drug Administration ("FDA") pursuant to section 510(k) of the Food, Drug, and Cosmetic Act ("FDCA") to market the initial version of Penuma. FAC ¶ 42. Before FDA clears a device for commercial distribution under section 510(k), an applicant must submit a premarket notification to FDA demonstrating that the device is "substantially equivalent" to a legally marketed device, which FDA then reviews and must clear prior to commercialization. 21 C.F.R. §§ 807.92, 807.100. "Substantial equivalence" means FDA has concluded on the basis of the information submitted that the device has the same intended use as the predicate

device and has either the same technological characteristics as the predicate device, or if it has different technological characteristics, the information submitted demonstrates that ***the device is as safe and effective as the predicate device*** and does not raise different questions of safety and effectiveness than the predicate device. 21 C.F.R. § 807.100(b) (emphasis added).[1]

National Medical Devices, Inc. submitted its premarket notification for a "Silicone Block" in 2004 on the basis that the device was substantially equivalent to an "ear, nose, and throat synthetic polymer material" used as a "space-occupying substance in the reconstructive surgery of the head and neck." FAC ¶ 42. FDA granted clearance to market the device "for use in the cosmetic correction of soft tissue deformities, [] contoured at the surgeon's discretion to create a custom implant to aid in the reconstruction process." *Id.*

IMD submitted a second premarket notification in 2016 for a "Pre-Formed Penile Silicone Block," relying on the previously cleared Silicone Block as the predicate device. FAC ¶ 43. FDA's Division of Reproductive, Gastro-Renal, and Urological Devices cleared the device for marketing for the indicated use of "cosmetic correction of soft tissue deformities, [] contoured at the surgeon's discretion to create a custom implant." *Id.* IMD made design changes and submitted another premarket notification in 2018, and again received FDA clearance to market the device for this same use. *Id.*

On March 15, 2022, IMD made another 510(k) submission that described the indicated use as follows: "intended for use in augmentation, reconstructive, and cosmetic surgery, and is contoured at the surgeon's discretion to create a custom implant. When used in augmentation procedures, the device provides cosmetic

[1] The Penuma is a Class II medical device. FAC ¶ 42. Devices that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential unreasonable risk of illness or injury are designated Class III medical devices and are subject to the more stringent premarket approval process. 21 U.S.C. § 360c(a)(1)(C).

augmentation of the penis and is intended for aesthetic purposes." Request for Judicial Notice ("RJN"), Ex. A, Ex. B at 3. The predicate device was the previously-cleared Penuma device. RJN, Ex. B at 4. The premarket notification accepted by FDA stated that "[t]he subject and predicate devices have the same intended use, as both are intended to be implanted in the penis as a space-occupying substance in cosmetic surgeries." *Id.* at 5. On May 13, 2022, FDA issued its clearance letter allowing marketing of the device for this use. *Id*. at 1-2. In other words, the intended use for the Penuma cleared by FDA on May 13, 2022, is "substantially equivalent" to the intended use for the Penuma cleared by FDA in 2004, 2017, and 2019. FDA's multiple clearances of the Penuma for marketing reflects its determination that the device is as safe and effective as the predicate legally marketed device. 21 C.F.R. § 807.100(b)(2)(ii)(B).

According to the FAC, Dr. Elist, who developed the surgical procedure for implanting the Penuma, has performed the procedure "thousands" of times. FAC ¶ 2. The Penuma is available only through prescription by a licensed physician. RJN, Ex. B at 3 (noting "prescription use" on FDA Form 3881).

B. Peña's experience with the Penuma implant

Peña alleges that while browsing the internet he "saw advertisements for the Penuma device and procedure, including Dr. Elist's website." FAC ¶ 22. Peña contends that after reading these advertisements he believed the Penuma "had been approved by the FDA, and this belief gave him a sense of comfort that the device was safe and effective" for "men like him who had normal penises, but simply wanted their penises to be larger." FAC ¶ 23. According to Peña, these advertisements led him to believe the Penuma procedure was "permanent and completely reversible" with "no adverse consequences from removal," and that the procedure would give him a "natural looking penis." FAC ¶¶ 24-25.

In October 2020, over a period of a few days, Peña met with Dr. Elist and his

staff, completed a questionnaire, and Dr. Elist implanted the Penuma.[2] FAC ¶ 26. Peña alleges that following surgery his penis did not look or feel natural, he lost sensation and experienced pain, particularly during intercourse, the implant eventually punctured the skin, and he had difficulty sleeping for three months. FAC ¶ 28.

Peña subsequently consulted a surgeon in Austin, Texas, and had the Penuma removed. FAC ¶ 29. Following removal, he allegedly experienced retraction of his penis, loss of sensation, and scarring. *Id*. As a result of his experience, Peña concluded that the Penuma device and procedure have "no value" for anyone and are "not safe or effective for healthy men with normal penises[.]" FAC ¶ 30.

C. Peña's allegations regarding Penuma advertising

Although Peña says he "saw advertisements" about the Penuma and procedure on Dr. Elist's clinic website (FAC ¶ 22), he does not say which advertisements he read or when he read them.[3] The FAC contains archived screenshots of two different webpages from Dr. Elist's clinic website (the only website Peña says he viewed).[4] The first screenshot (man in suit) contains the heading "Penile Enlargement Surgery" followed by the brief statement: "Enhance and enlarge the length, girth, and size of your penis. Looks, feels, and functions just like nature intended – just significantly larger." FAC ¶ 51, Figs. 5, 7. The archived hyperlinks for this webpage, which are cited in the FAC (*see id*.), show that the page contains much more information than the screenshots capture. For example, it includes a section with the heading "Benefits of the Penuma® Silicone Implant ***May*** Include," followed by a list of potential

[2] Peña contacted Dr. Elist's office as early as July 2020. RJN, Ex. C at 1.
[3] The FAC contains numerous screenshots of advertisements from Dr. Elist's clinic website as well as other websites, Twitter, and Instagram. *See* FAC ¶¶ 48, 50, 51 & Figs. 1-11.
[4] The FAC contains five archived screenshots in all from Dr. Elist's clinic website, www.drelist.com. Four of the screenshots are of the same webpage (man in suit), archived as it appeared in 2019, 2020, 2021, and on some other unknown date. FAC ¶ 49, Fig. 1; FAC ¶ 51, Figs. 5, 7, 9. The fifth screenshot is of a different webpage as it appeared in 2020. FAC ¶ 51, Fig. 4. Because Peña received the Penuma implant in October 2020, only the screenshots from 2019 (Fig. 5) and 2020 (Figs. 4, 7) could be potentially relevant to his claims.

benefits, among them "[o]bserved increases in penile size of 1.5 to 2.5 inches ***on average****." RJN, Ex. D. at 1 (emphasis added). The asterisk at the end of this statement identifies the following disclaimer appearing further below the statement: "***Not a guarantee of individual results***." *Id.* (emphasis added).

Three separate places on this webpage—including immediately below the statement pictured in Figures 5 and 7 of the FAC—there is a hyperlink entitled "Learn More." In each instance this links to another webpage entitled "Penile Enlargement" that contains more information about the Penuma and the procedure. RJN, Ex. E. This webpage discusses possible benefits and complications of the procedure. *Id.*

The first section of this linked-to webpage, "Penile Enlargement Surgery," states that the Penuma implant "***can*** produce a natural look, ***potentially*** adding girth and flaccid length to the penis. Individual results may vary." *Id.* at 1 (emphasis added). Further down the page, other sections state that "[t]hese implants ***can often*** address penile size problems" and "***may*** offer men other ***possible*** benefits, including … ***[p]otential*** increases in penile girth and flaccid length." *Id.* (emphasis added). The statement "individual results may vary" appears ***four*** times on this page, along with "There are no guaranteed outcomes." *Id.* at 1-2. The page states specifically that anticipated increases in erect length, "***if any***, can take 6-12 months or longer after surgery, depending on the patient's anatomy." *Id.* at 2 (emphasis added). The reader is advised that "the first step in finding out more about penis enlargement surgery is to meet with [Dr. Elist's staff] for a private consultation" and that "[d]uring the pre-operative phase, our medical team will determine if you are a candidate for the procedure." *Id*. at 1-2.

Another section of the same page, "Side Effects and Complications," lists as possible side effects inflammation, swelling, bruising, erection pain, changes in sensation, penile retraction, infection, and the possible need for removal and later reinsertion. *Id.* at 1. It further states that "[i]f complications occur, they are mostly due

to patient noncompliance" and "[a]s with all surgical procedures, recovery from penile enhancement varies from patient to patient." *Id.* at 1.

Three different places on the webpage state that at the pre-operative consultation "[a] detailed list of potential complications, risks, benefits, and alternatives, including no surgery, will be discussed as well as reasonable post-operative expectations," or similar language. *Id.* at 1. This "detailed list" of the potential risks and complications includes the specific adverse consequences Peña alleges he experienced and/or was not informed about, including, for example, "patient … dissatisfaction with results," "extended penile … pain and discomfort," "lack of sensation on parts of penis," "moderate to severe scar tissue formation," "penile shortening and/or possible penile/implant misalignment," "penile deformity," "penile retraction in erect and flaccid states," and "removal of implant may result in penile retraction, scar formation, and other potential complications, necessitating additional treatment." RJN, Ex. F at 2-3. Peña acknowledged each of these risks in writing before his procedure, *id.* at 7-8, as well as that "no promises or guarantees" were made to him regarding the outcome of his surgery, *id.* at 4-5. He also acknowledged that any questions he had regarding the possible risks and complications were answered to his satisfaction. *Id.* at 2, 4.

The screenshot of the second webpage from Dr. Elist's clinic website, pictured in Figure 4 of the FAC, captures only a limited portion of the webpage that appears nearly halfway down the page. RJN, Ex. G. Before getting to the information in the screenshot, the reader is informed ***twice*** that results of the procedure may vary, ***twice*** that the possible risks, complications, benefits, and alternatives will be discussed in advance, and that "[a]n initial consultation with one of our personal consultants followed by a consultation with Dr. Elist will help you assess whether this procedure is right for you." *Id.* Further down the page, after the screenshot pictured in the FAC, a section entitled "Penuma® Surgery" states:

> This implant is designed to enhance the girth and flaccid length of the penis, but individual results may vary. During your consultation with Dr. Elist, he will go over all possible complications, risks, benefits, as well as surgical and non-surgical alternatives. Keep this in mind when reviewing before and after photographs, as well as viewing and reading testimonials from other patients.

Id. Yet another section further down the page with the heading "Are There Any Potential Risks Associated With The Penuma® Implant?" identifies a potential risk for infection and fluid build-up, and states again that "[a] detailed list of potential complications, risks, benefits, and alternatives, including no surgery, will be discussed in advance." *Id.*

The FAC references several medical journal articles that collectively contain reports of a very small number patients who underwent removal surgery or experienced complications following penile implant surgery, some of whom received the Penuma implant. RJN, Ex. I through Ex. L.[5] None of these articles states that the risk of removal with the Penuma differs from what is discussed in the 2018 peer-reviewed study published in the Journal of Sexual Medicine by Dr. Elist and his colleagues (cited in the FAC) (RJN, Ex. H) ("the Penuma study"). Nor do these articles identify complications different from those Dr. Elist instructs his patients about during pre-operative counseling.[6] For example, the Furr study examined only four silicone implant patients, and it is not clear from the article that any of these patients received the Penuma.[7] RJN, Ex. I at 3-4. Even if they did, there is no

[5] Another article cited in the FAC, Marra et al., does not discuss silicone implants, much less the Penuma.

[6] Notably, 7 of the 12 patients in the Penuma study who underwent removal (out of 400 total patients) returned after 4 to 6 months to have the Penuma reinserted. RJN, Ex. H at 6.

[7] The Furr study discusses silicone penile implants in general of which the Penuma is just one type. The Penuma study is mentioned.

indication that Dr. Elist was the surgeon. Similarly, the Kapadia article, cited as reporting certain complications (FAC ¶ 65), discusses only three patients who received the Penuma but specifically states that "[a]ll patients underwent extensive pre-operative counseling of complications including damage to neurovascular structures resulting in new or persistent sensory loss, ED [erectile dysfunction], loss of penile length and girth, atrophy, scarring, and poor cosmesis." RJN, Ex. K at 2.

Peña brings claims under the False Advertising Law, Cal. Bus. & Prof. Code § 17500 ("FAL"), Consumers Legal Remedies Act, Cal. Civ. Code § 1750 ("CLRA"), and the Unfair Competition Law, Cal. Bus. & Prof. Code § 17200 ("UCL"). Among other relief, Peña seeks actual damages, punitive damages, restitution, disgorgement, and an injunction against Defendants' allegedly deceptive advertising, on behalf of himself and a proposed nationwide class of consumers who purchased the Penuma implant and had the surgery performed by Dr. Elist in Beverly Hills. FAC ¶¶ 86, 104, 105, 117, 118, Prayer.

LEGAL STANDARD

A court should dismiss a complaint if it fails to set forth "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *Ashcroft v. Iqbal*, 556 U.S. 662, 697 (2009). The pleading standard "demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation" and more than "labels and conclusions." *Iqbal*, 556 U.S. at 678. Mere legal conclusions are not "facts" for Rule 8 purposes. *Id.* at 678-79; *Twombly*, 550 U.S. at 555. Nor is it enough to allege facts "merely consistent with" liability or showing only that entitlement to relief is *possible*. *Iqbal*, 556 U.S. at 678; *Twombly*, 550 U.S. at 557. The factual allegations "must be enough to raise a right to relief above a speculative level." *Twombly*, 550 U.S. at 555. "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has

alleged—but has not 'show[n]'—that the pleader is entitled to relief." *Iqbal*, 556 U.S. at 679 (quoting Fed. R. Civ. P. 8(a)(2)).

Any claims grounded in fraud must be pleaded with particularity under Rule 9(b), including claims based on concealment or omission theories. *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1125-26 (9th Cir. 2009). This also includes UCL claims that may be labeled as unfair- or unlawful-practice claims when those claims are grounded in fraud. *Id.*

ARGUMENT

I. Peña has not stated a claim for violation of the consumer-protection statutes.

Peña's FAL, CLRA, and UCL claims are all grounded in fraud and so must be pleaded with particularity.[8] *Kearns*, 567 F.3d at 1125. "In a deceptive advertising case, Rule 9(b) requires that the plaintiff[] identify specific advertisements and promotional materials; allege when the plaintiff[] w[as] exposed to the materials; and explain how such materials were false or misleading." *Janney v. Gen. Mills*, 944 F. Supp. 2d 806, 818 (N.D. Cal. 2013). Under the reasonable consumer standard, Peña must show that "members of the public are likely to be deceived." *Williams v. Gerber Prods. Co.*, 552 F.3d 934, 938 (9th Cir. 2008). "This requires more than a mere possibility that [the advertisement] might conceivably be misunderstood by some few consumers viewing it in an unreasonable manner." *Ebner v. Fresh, Inc.*, 838 F.3d 958, 965 (9th Cir. 2016) (cleaned up). "Rather, the reasonable consumer standard requires a probability that a significant portion of the general consuming public or of targeted consumers, acting reasonably in the circumstances, could be misled." *Id.* (cleaned up).

[8] Although Peña refers to "unlawful" and "unfair" acts in his UCL cause of action, as discussed in section I.D, those allegations purportedly are based on violations of the FAL and CLRA, and unspecified violations of the FDCA and the California Sherman Food, Drug, and Cosmetic Law ("Sherman Act"). *See, e.g.*, FAC ¶¶ 110, 112. Because the FAC does not allege any basis for violation of these statutes other than the alleged fraudulent conduct, Rule 9(b) applies to the entire complaint. *Kearns*, 567 F.3d at 1125; *Chong v. Nestlé Waters N. Am., Inc.*, 2020 WL 7690175, at *5 (C.D. Cal. Nov. 30, 2020).

Peña's claims fall short of these requirements.

A. The FAC fails to plead with particularity as Rule 9(b) requires.

Peña alleges that "[w]hile browsing the Internet, [he] saw advertisements for the Penuma device and procedure, including Dr. Elist's website." FAC ¶ 22. However, Peña does not identify any particular advertisements he read on Dr. Elist's clinic website, much less relied upon. Although the FAC contains screenshots of advertisements from various websites and social media, Peña does not identify any that he *read*, nor does he say *when* he read them or *how* he was misled by them. This is fatal to all of his claims under Rule 9(b). *Kearns*, 567 F.3d at 1126; *Gutierrez v. Johnson & Johnson Consumer Inc.*, 2021 WL 822721, at *4-5 (S.D. Cal. Jan. 22, 2021); *Herrara v. Estee Lauder Cos.*, 2012 WL 12507876, at *4 (C.D. Cal. Sept. 20, 2012); *Thornton v. Micro-Star Int'l Co.*, 2017 WL 10621210, at *7 (C.D. Cal. Aug. 21, 2017).

The FAC is also deficient because it is an impermissible "shotgun" pleading that "uses the omnibus term 'Defendants' throughout the complaint by grouping defendants together without identifying what the particular defendants specifically did wrong." *Morris v. Sun Pharma Global Inc.*, 2021 WL 3913191, at *3 (C.D. Cal. May 13, 2021) (citing *Solberger v. Wachovia Sec., LLC*, 2010 WL 2674456, at *4 (C.D. Cal. June 30, 2010)); *see Aranda v. County of Los Angeles*, 2020 WL 913422, at *7 (C.D. Cal. Feb. 6, 2020) (finding that plaintiff "impermissibly lump[ed] together claims and defendants"). Peña lumps together all five of the Defendants throughout the facts section as well as the sections setting forth each cause of action, failing to identify the specific actions of each Defendant. *See generally* FAC. This not only violates Rule 8, but also Rule 9(b)'s requirement to plead fraud-based claims with particularity. *Destfino v. Reiswig*, 630 F.3d 952, 958 (9th Cir. 2011) (Rule 9(b) "does not allow a complaint to … lump multiple defendants together but require[s] plaintiffs to differentiate their allegations when suing more than one defendant.") (quoting

Swartz v. KPMG LLP, 476 F.3d 756, 764-65 (9th Cir. 2007))); *Drake v. Toyota Motor Co.*, 2020 WL 7040125, at *10-11 (C.D. Cal. Nov. 23, 2020) (finding "sweeping and conclusory allegations" that Defendants were acting in concert insufficient as a matter of law).

Peña tries to justify his shotgun pleading by alleging that Defendants are subject to joint enterprise liability for the marketing of the Penuma. But those allegations are entirely conclusory and fail as a matter of law. "To establish a joint venture[9] under California law, Plaintiff[] must show an agreement between the parties under which they have a community of interest, that is, a joint interest, in a common business undertaking, an understanding as to the sharing of profits and losses, and a right of joint control." *Ratha v. Phatthana Seafood Co.*, 35 F.4th 1159, 1173 (9th Cir. 2022) (cleaned up). Although Peña alleges common ownership by Dr. Elist as to IMD and Menova, the FAC does not allege facts showing the existence of any agreement to which each of the five Defendants is a party, much less an agreement that addresses sharing of profits and losses and a right of joint control over the "enterprise" by all Defendants. The only agreement mentioned in the FAC is between IMD and Gesiva to distribute the Penuma implant (FAC ¶ 35), and there are no allegations that this agreement discusses sharing of profits and losses or a right to jointly control the marketing or sale of Penuma. Accordingly, the FAC does not allege facts showing the existence of a joint enterprise. The FAC fails to comply with the Federal Rules of Civil Procedure and, accordingly, should be dismissed.

B. Peña has failed to plead an actionable misrepresentation.

Even assuming he read them, Peña also has not plausibly alleged that either of the pages from Dr. Elist's clinic website pictured in the FAC are false or misleading when the pages are read in their entirety and in context. Moreover, Peña has failed to

[9] California courts use the terms "joint enterprise" and "joint venture" interchangeably. *See Jackson v. East Bay Hosp.*, 246 F.3d 1248, 1261 (9th Cir. 2001).

allege facts supporting his conclusion that the Penuma implant and procedure are not safe or effective, or that Defendants misrepresented the FDA-cleared use of the Penuma.

1. *Dr. Elist's clinic website is not false or misleading.*

Peña received the Penuma implant in October 2020. FAC ¶ 26. As a result, the pages from Dr. Elist's clinic website that are potentially relevant are those pictured in FAC ¶ 51, Figs. 4, 5, and 7. Peña has selectively referenced only one small portion of each webpage to create the impression that the website leads consumers to believe that every man who chooses to undergo the Penuma implant procedure will experience a larger yet natural-looking penis, and that there are no risks or potential complications associated with the procedure. No reasonable consumer could read these webpages and reach that conclusion. *See Naimi v. Starbucks Corp.*, 2018 WL 11255596, at *6 (C.D. Cal. Feb. 28, 2018) ("[I]n determining whether a reasonable consumer would have been misled by a particular advertisement, context is crucial.") (quoting *Fink v. Time Warner Cable*, 714 F.3d 739, 742 (2d Cir. 2013)); *Holt v. Noble House Hotels & Resort, Ltd.*, 370 F. Supp. 3d 1158, 1167-68 (S.D. Cal. 2019) ("Under Ninth Circuit precedent, district courts have found that a reasonable consumer would not be misled when "statements, in context, are not misleading," or where "[a]ny ambiguity that [reasonable consumers] would read into any particular statement is dispelled by the promotion as a whole." (citing *Freeman v. Time, Inc.*, 68 F.3d 285, 290 (9th Cir. 1995)).

The archived webpage pictured in Figures 5 and 7, which is Dr. Elist's homepage, contains a link to the "Penile Enlargement" page with the lead-in: "Enhance and enlarge the length, girth, and size of your penis. Looks, feels, and functions just like nature intended – just significantly larger." RJN, Ex. D at 1, 3. When the reader clicks the "Learn More" link, the Penile Enlargement page states clearly and repeatedly that increases in penile size are *possible*, but individual results

can vary, and there are no guaranteed outcomes. RJN, Ex. E at 1-2. Indeed, this information is repeated in other pages on the website. Thus, Peña's reading of the single lead-in statement or "headline" (in Figures 5 and 7) in isolation is unreasonable.

The Penile Enlargement page further identifies a number of possible side effects and complications, including the need for possible removal; it informs the reader that more information will be provided at a pre-operative counseling session to "determine if you are a candidate for the procedure"; and it states at least ***three*** times that "[a] detailed list of the potential complications, risks, benefits, and alternatives, including no surgery, will be discussed as well as reasonable post-operative expectations," or similar language. *Id.* at 1.

The second webpage from Dr. Elist's clinic website, from which the screenshot in Figure 4 of the FAC is taken, states ***four*** times that the results of the procedure may vary (including an additional disclaimer at the end of the page). RJN, Ex. G (stating, for example: "This implant is designed to enhance the girth and flaccid length of the penis, but individual results may vary."). It states multiple times that the Penuma "***may*** increase both the penile girth and flaccid length" (or similar wording), describing these as "***potential*** benefits." *Id.* (emphasis added). Even the portion of the page pictured in the FAC states that the features of the Penuma include "***[p]otential*** increases in penis width and flaccid length." FAC ¶ 51, Fig. 4 (emphasis added). Similarly, this page states ***four*** times that all possible risks, complications, benefits, and alternatives will be discussed in advance. *Id.* Reasonably read, the information on the website is an overview of the procedure and an invitation to the reader to learn more by contacting Dr. Elist's clinic.

Peña simply has not alleged facts showing that Defendants promised him a larger penis rather than the *possibility* of a larger penis. Nor has Peña alleged facts showing that Defendants promised him a surgery that would be free from any complications or the potential need to have the implant removed. Reasonable

consumers would understand after reading the website that further information regarding the possible benefits and risks of the procedure would be presented during the pre-operative counseling session. *Naimi*, 2018 WL 11255596, at *6; *Holt*, 370 F. Supp. 3d at 1167-68.

2. *Peña lacks factual support for his claims that the Penuma is not safe or effective*.

Peña likewise has not provided facts to support his allegations regarding the Penuma's safety and effectiveness. Peña alleges that "[t]here is no evidence that the Penuma device makes patients' non-erect penises longer." FAC ¶ 36. However, the FAC does not allege specific facts showing that the Penuma procedure fails to provide this benefit, only that the procedure does not result in increased length for everyone—which is consistent with the representations on Dr. Elist's clinic website and the pre-operative counseling Peña received.

Peña's allegation that the advertising falsely states that the procedure results in a "natural-looking" penis is similarly unsupported. He asserts that the procedure "often results in abnormal and deformed-looking penises" (FAC ¶ 25), but he has not pleaded specific facts showing this occurs often, and the website makes clear there are no guaranteed results.

He also contends that the Penuma device "frequently causes complications that require the implant to be removed[.]" FAC ¶ 52. Again, however, the FAC alleges no facts showing that removal has been frequent, and the published study involving 400 patients cited in the FAC indicates that the removal rate is only 3%. RJN, Ex. H at 1. Peña cites no facts indicating the removal rate is higher or that the potential need for removal was misrepresented to him at his pre-operative consultation.

Peña similarly alleges that the Penuma procedure "frequently causes scarring, resulting in the penis becoming shorter," "many patients experience a penguin or batwing shape post-surgery," and "many patients experience sexual dysfunction,

including loss of sensation." FAC ¶¶ 53-54, 56. Likewise, he alleges that the procedure "frequently causes painful infections that lead to yet more scarring." *Id.* ¶ 63. Again, the FAC cites no medical literature or other facts showing that these adverse events are frequent.

Although the FAC cites a few articles indicating that some patients who received silicone penile implants have experienced complications, even assuming that all of the patients in these articles who received such implants received the Penuma—which is not evident—these articles (excluding the Penuma study) represent fewer than 15 patients. Peña has not alleged facts showing that this small number of anecdotal reports of complications—out of the thousands of procedures performed by Dr. Elist—indicate any greater risk than the disclosures made by Dr. Elist and his staff before his surgery.

Peña does not allege that Dr. Elist and his staff failed to discuss with him the "detailed list" of the potential complications, risks, benefits, and alternatives (as referenced on Dr. Elist's clinic website) before he underwent the surgery. To the contrary, Peña's signed consent form shows this discussion did occur and that Peña understood there are numerous risks and no guaranteed outcomes. RJN, Ex. F. Moreover, the Kapadia article cited in the FAC indicates that Penuma patients receive "extensive pre-operative counseling," including the risk of possible "damage to neurovascular structures resulting in new or persistent sensory loss, ED [erectile dysfunction], loss of penile length and girth, atrophy, scarring, and poor cosmesis." RJN, Ex. K at 2. Given the references to pre-operative counseling on the website and in the cited medical literature (of which the Court may take judicial notice), and Peña's failure to allege facts showing that the reports in the medical literature are inconsistent with the information provided during his pre-operative counseling, Peña has not "nudged [his] claims across the line from conceivable to plausible[.]" *Twombly*, 550 U.S. at 570. Revise motion to insert cited pages from exhibits.

3. *The statement regarding the FDA-cleared use of the Penuma is not false or misleading.*

Although Peña does not allege he personally saw any advertisement making this claim before he paid for the Penuma implant and procedure, he contends that the phrase "the first FDA-cleared penile implant for cosmetic enhancement," which has appeared on certain Defendants' websites and social media, misleads consumers into believing that the implant is FDA-cleared and safe and effective for use in men with "normal" penises.[10] FAC ¶¶ 48, 50, 51 at Figs. 2, 3. Peña claims this is misleading because the specific indication for use cleared by FDA (at that time) was "cosmetic correction of soft tissue deformities." FAC ¶¶ 42-43. In Peña's view, the phrase "soft tissue deformities" applies only to certain "serious medical conditions that can cause significant pain and prevent men from having sexual intercourse, in addition to shortening the penis." FAC ¶ 45. But Peña alleges no facts showing that FDA has limited the use in this manner or that reasonable consumers would construe it this way. Neither Dr. Elist nor FDA defined "soft tissue deformities" for purposes of the 510(k) submission.

Merriam-Webster defines "deformity" as an "imperfection, blemish, such as a physical blemish or distortion," "disfigurement," or "a moral or aesthetic flaw or defect." Merriam-Webster Dictionary, *Definition of "Deformity," available at* https://www.merriam-webster.com/dictionary/deformity. Thus, a deformity is not

[10] Peña also alleges that after reading certain unspecified advertisements he believed the Penuma implant "had been approved by the FDA, and this belief gave him a sense of comfort that the device was safe and effective." FAC ¶ 23. But the webpages in the FAC from Dr. Elist's clinic website—the only website Peña claims to have viewed—do not mention FDA. Even so, Peña has not identified any advertisement with the term "FDA-approved," only "FDA-***cleared***," which has a different meaning. *Repro-Med Sys., Inc. v\. EMED Techs. Corp.*, 2019 WL 1427978, at *3 (E.D. Cal. Mar. 29, 2019) ("***Clearance*** is the FDA term applied to devices which the FDA has determined are substantially equivalent to existing devices already in the marketplace; ***approval*** is the FDA term applied to a device that has been reviewed and vetted to the highest degree.") (cleaned up).

limited to a serious disfiguring condition that impairs function; it can also include "aesthetic flaws."

Peña does not allege facts showing that reasonable consumers interested in the Penuma would view "cosmetic enhancement" of the penis as materially different from "cosmetic correction" of aesthetic flaws in the penis. The existence of a flaw or defect involves the perception of the patient. Indeed, Peña, who now says his penis was "normal" before the surgery, indicated on his eligibility questionnaire months before the surgery that he considered his penis "slightly defective" in appearance.[11] RJN, Ex. F at 3. Men considering the Penuma implant believe their penises have at a minimum some aesthetic flaw (e.g., too small, not long enough) for which they seek this procedure. As a result, Peña has not alleged facts showing that reasonable consumers interested in the Penuma would draw the distinction he has regarding the description of its FDA-cleared use.

FDA apparently does not see a material difference in the uses either. Earlier this year, FDA cleared the Penuma for the following indicated use after IMD submitted a 510(k) premarket notification with a more detailed description of the use: "The Pre-Formed Penile Silicone Block is intended for use in augmentation, reconstructive, and cosmetic surgery, and is contoured at the surgeon's discretion to create a custom implant. When used in augmentation procedures, the device provides cosmetic augmentation of the penis and is intended for aesthetic purposes." RJN, Ex. B at 1-3. The 510(k) Summary submitted by IMD informed FDA that the design of the Penuma had not changed from 2019 (the year of the previous FDA clearance), and that this

[11] The Penuma study, published two years before Peña's surgery, explains that the Penuma was developed "for the correction of the penis in patients presenting with a ***perception of small penis***, a buried penis from prepubic recession, micropenis, and other related diagnoses." RJN, Ex. H at 2 (emphasis added). As Dr. Elist and his colleagues stated: "Many of our patients had a penis that would have been considered normal by statistical standards. However, in the patient's mind, his appearance is flawed. Therefore, it is the degree to which the perceived flaw becomes debilitating that may define patients who are or are not appropriate candidates for this procedure." *Id.* at 6.

device and the previously-cleared device "have the same intended use, as both are intended to be implanted in the penis as a space-occupying substance in cosmetic surgeries." *Id.* at 5.

For all these reasons, Peña has not alleged that the advertising for the Penuma is false or misleading.

C. Peña has failed to plead an actionable omission.

To the extent Peña's claims are based on alleged omissions—and setting aside Peña's failure to identify any specific advertisements he relied on—these claims fail as well. There is no generalized duty to disclose, and so a plaintiff alleging a concealment claim must plead facts establishing that the defendant owed such a duty to the plaintiff. *Hodsdon v. Mars, Inc.*, 891 F.3d 857, 861 (9th Cir. 2018). Under California law, this duty can exist only in four circumstances: (1) a fiduciary relationship; (2) the defendant has exclusive knowledge of material facts; (3) the defendant actively conceals a material fact from the plaintiff; and (4) the defendant makes partial representations but also suppresses some material facts. *LiMandri v. Judkins*, 52 Cal. App. 4th 326, 336 (1997). Peña does not allege (nor could he) that Defendants owed him a fiduciary duty, nor does he allege facts stating a claim under any of the other categories.

First, the FAC belies that Defendants had exclusive knowledge of material facts not known to Peña. It references multiple publications and medical websites that discuss patients who experienced complications following penile implant surgery that required removal, resulting in, for example, "penile shortening, fibrosis, and sexual dysfunction." *See, e.g.*, FAC ¶¶ 37, 55, 65, 66; RJN, Ex. H through Ex. L. Similarly, the specific description of the FDA-cleared use of the Penuma was publicly available on FDA's website, and in the Penuma study (published in 2018 in the Journal of Sexual Medicine) (cited in the FAC). RJN, Ex. M at 3; Ex. H at 2.

The allegations in the FAC along with the cited and judicially noticeable sources demonstrate that these facts were "not within the exclusive knowledge of Defendants but available to the public." *Andren v. Alere, Inc.*, 207 F. Supp. 3d 1133, 1142-43 (S.D. Cal. 2016) (dismissing similar omission-based claims in medical device case); *see Shapiro v. AT&T Mobility, LLC*, 2021 WL 4798726, at *3-4 (C.D. Cal. July 28, 2021) (dismissing concealment claim when complaint showed information was publicly available); *Wolph v. Acer Am. Corp.*, 2009 WL 2969467, at *4 (N.D. Cal. Sept. 14, 2009) ("Based on Plaintiffs' own allegations, Plaintiffs have not alleged facts that show Acer had exclusive knowledge of the material facts and that Plaintiffs could not have reasonably discovered such facts.").

Second, Peña has not alleged any facts showing active concealment. A plaintiff must allege specific "affirmative acts on the part of the [D]efendants in hiding, concealing or covering up the matters complained of." *Andren*, 207 F. Supp. 3d at 1143 (citation omitted). Peña does not allege any facts showing that Defendants actively tried to conceal information concerning the FDA-cleared use or potential complications associated with the Penuma procedure; the allegations are entirely conclusory. *See, e.g.*, FAC ¶¶ 37, 47, 57 (alleging only that Defendants "actively concealed" the information). This is insufficient.

Finally, any claim based on a partial representation theory likewise fails. "[P]artial representation claims require affirmative representations, which are rendered misleading because qualifying information is withheld." *Patt v. Antech Diagnostics, Inc.*, 2020 WL 5076970, at *10 (C.D. Cal. May 18, 2020). As set forth in the previous section, Peña has not identified any advertisements that are misleading.

D. Peña fails to allege any "unlawful" or "unfair" practices under the UCL.

To the extent Peña alleges that Defendants have violated the UCL by committing an "unlawful" or "unfair" business practice, those claims also fall short.

Peña alleges that Defendants' advertising of the Penuma was "unlawful" in that it violated the FAL, CLRA, FDCA, and Sherman Act. FAC ¶ 110. As set forth in the previous sections, however, Peña has not alleged any actionable misrepresentation or omission and therefore has not alleged a violation of the FAL or CLRA. Similarly, Peña has not alleged any provision of the FDCA or Sherman Act that Defendants violated or explained how it was violated. To the extent those alleged statutory violations are also based on purported misrepresentations or omissions, they fail for the same reasons.

Any "unfair" practices claim suffers the same fate. Peña alleges that the Penuma advertising is "immoral, unethical, unscrupulous, and substantially injurious to consumers" and "violates public policy" by violating the above statutes. FAC ¶¶ 111-12. But Peña has not alleged any false or misleading statements and the FAC "does not suggest any other reason the [Penuma advertising] would be immoral, unethical, or otherwise satisfy the requirements for a UCL unfair prong claim[.]" *Chong*, 2020 WL 7690175, at *9. "[W]here the practice alleged to be unfair overlaps entirely with the practices addressed under the fraudulent and unlawful prongs of the UCL, the former may be dismissed when the latter prongs do not survive." *Knuttel v. Omaze, Inc.*, 2022 WL 1843138, at *13 (C.D. Cal. Feb. 22, 2022) (finding that plaintiff "allege[d] no facts distinct from her other claims that could support an unfairness claim under the UCL").

II. Peña's claims against IMD and Gesiva fail for additional reasons.

Peña's claims against IMD and Gesiva fail for the additional reason that IMD, as the manufacturer of the Penuma, and Gesiva, as its distributor, owed no duty to Peña. The Penuma is a prescription medical device. RJN, Ex. B at 3. Under the learned intermediary doctrine, a manufacturer's duty to warn in the case of a prescription medical device runs only to the physician, not the patient. *Plenger v. Alza Corp.*, 11 Cal. App. 4th 349, 361 n.6 (1992). This same duty applies to distributors.

See Jones v. Smithkline Beecham Corp., 2008 WL 11340340, at *3 n.4 (C.D. Cal. Aug. 19, 2008); *Maher v. Novartis Pharms. Corp.*, 2007 WL 2330713, at *4 (S.D. Cal. Aug. 13, 2007). The duty to warn is fulfilled by providing adequate warnings to the physician. *Plenger*, 11 Cal. App. 4th at 361 n.6. Pursuant to the learned intermediary doctrine, to prove causation, a plaintiff must allege that the inadequate warnings or lack of warnings regarding the risks of the medical device would have altered the physician's decision to use the device. *See Motus v. Pfizer, Inc.*, 196 F. Supp. 2d 984, 991, 995 (C.D. Cal. 2001), *aff'd*, 358 F.3d 659, 661 (9th Cir. 2004).

The learned intermediary doctrine applies to claims brought under California's consumer protection statutes when, as here, the claims are based on a failure to warn. *Andren*, 207 F. Supp. 3d at 1144 (finding that learned intermediary doctrine would apply to CLRA and UCL claims that defendants' marketing materials misrepresented the safety and effectiveness of a prescription medical device); *Saavedra v. Eli Lilly and Co.*, 2013 WL 3148923, at *3-4 (C.D. Cal. June 13, 2013) (same as to CLRA, FAL, and UCL claims involving safety of prescription drug). Because Peña does not allege that IMD and Gesiva failed to provide adequate warnings to Dr. Elist, his allegations against IMD and Gesiva fail as a matter of law.[12]

III. Peña's claims against Menova fail for additional reasons.

The claims against Menova fail additionally because the FAC does not allege that Menova had anything to do with the representations made in the Penuma advertising. Rather, the FAC alleges that Menova "own[s] the Penuma trademark and all intellectual property rights associated with the device," and that Menova and Dr. Elist "authorized" IMD and Gesiva to contract with certain urologists around the country to perform Penuma implantation procedures and use the Penuma trademark.

[12] Peña could not state a claim against IMD or Gesiva in any event because (1) he cannot plausibly allege that Dr. Elist (as the owner of IMD) failed to warn himself of the Penuma's risks and indicated uses; and (2) he alleges that Dr. Elist was fully aware of this information. As a result, Peña cannot plausibly allege that IMD or Gesiva failed to provide warnings that would have altered Dr. Elist's decision to prescribe the Penuma for Peña.

FAC ¶¶ 34-35. These activities are unrelated to Peña's claims, which are limited to representations made about Penuma, and implantation procedures performed by Dr. Elist. The Court should dismiss Menova on this additional ground.

IV. The Court should dismiss Peña's claims for equitable relief.

Peña likewise is not entitled to any equitable relief. As an initial matter, any claim for equitable relief requires a plaintiff to plead facts that, if proven, would show legal remedies would be inadequate. *Sonner v. Premier Nutrition Corp.*, 971 F.3d 834, 841-44 (9th Cir. 2020); *Klaehn v. Cali Bamboo LLC*, 2022 WL 1830685, at *3 (9th Cir. June 3, 2022) (finding *Sonner* was properly applied to dismiss UCL equitable claims at pleading stage for failure to allege lack of adequate legal remedy, and rejecting argument that UCL remedies are cumulative to other remedies and adequacy of legal remedies cannot be known until trial). Any state rule to the contrary does not apply in federal court. *Sonner*, 971 F.3d at 841-44. The question is not whether Peña is likely to succeed on his legal claims (as shown above, he isn't). Rather, the question is whether, assuming Peña *did* prevail, the legal remedy would be adequate. *See Madrigal v. Hint, Inc.*, 2017 WL 6940534, at *4 (C.D. Cal. Dec. 14, 2017) (holding that if plaintiffs ultimately could not recover, that would not necessarily mean a legal remedy was inadequate, "only that their claim lacks merit"). "[T]here is nothing in the [FAC] to suggest that monetary damages would not make [Peña] or the putative class whole." *Gibson v. Jaguar Land Rover N. Am., LLC*, 2020 WL 5492990, at *3 (C.D. Cal. Sept. 9, 2020); *Clark v. Am. Honda Motor Co.*, 528 F. Supp. 3d 1108, 1120-21 (C.D. Cal. 2021) (same). The failure to plead the lack of an adequate legal remedy bars all forms of equitable relief, including injunctive relief. *Id.* at 1120-22 (collecting cases); *PDF Print Commc'ns Inc. v. Federated Mut. Ins. Co.*, 2022 WL 2189631, at *3 (C.D. Cal. Mar. 29, 2022); *Adams v. Cole Haan, LLC*, 2020 WL 5648605, at *2 (C.D. Cal. Sept. 3, 2020); *Gibson*, 2020 WL 5492990, at *3.

Peña may contend that he is seeking equitable relief in the alternative to his legal claims, but that will do him no good. Although alternative pleading is permitted, a plaintiff must still comply with the requirements for each alternative. *See, e.g.*, *Drake v. Toyota Motor Co.*, 2020 WL 7040125, at *14 (C.D. Cal. Nov. 23, 2020); *Loo v. Toyota Motor Sales, USA, Inc.*, 2020 WL 4187918, at *8 (C.D. Cal. Apr. 10, 2020). For equitable claims, one of those requirements is pleading facts that, if proven, would show the legal remedy is inadequate. *See, e.g.*, *Goldstein v. Gen. Motors LLC*, 517 F. Supp. 3d 1076, 1088 (S.D. Cal. 2021) (rejecting "alternative" pleading of UCL claim by plaintiffs who failed to allege facts showing legal remedy was inadequate); *Drake*, 2020 WL 7040125, at *14 (same); *Loo*, 2020 WL 4187918, at *8 (same). Peña has not done so here, and he cannot ask the Court to consider new facts that he did not and could not actually plead in the operative complaint. Under *Sonner*, Peña must plead that he lacks an adequate remedy at law. *Franckowiak v. Scenario Cockram USA, Inc.*, 2020 WL 9071697, at *2 (C.D. Cal. Nov. 30, 2020).

Moreover, Peña does not premise his claims for equitable relief on a different factual theory, as required for alternative pleading. *Rodriguez v. Just Brands USA, Inc.*, 2021 WL 1985031, at *8 (C.D. Cal. May 18, 2021) (finding that "legal and equitable claims based on the same factual predicates are not true alternative theories of relief but rather are duplicative") (quoting *Madrigal*, 2017 WL 6940534, at *5); *Loo*, 2020 WL 4187918, at *7 (same).

Peña also lacks standing to seek injunctive relief because he has not alleged that he will suffer a repeated injury. To have standing, Peña must show that "he has suffered or is threatened with a concrete and particularized legal harm, coupled with a sufficient likelihood that he will again be wronged in a similar way." *Bates v. United Parcel Serv., Inc.*, 511 F.3d 974, 985 (9th Cir. 2007) (cleaned up). Peña "must demonstrate 'a real and immediate threat of repeated injury' in the future." *Chapman v. Pier 1 Imports (U.S) Inc.*, 631 F.3d 939, 946 (9th Cir. 2011) (quoting *O'Shea v.*

Littleton, 414 U.S. 488, 496 (1974)). The threat of future injury must be "actual and imminent, not conjectural or hypothetical." *Summers v. Earth Island Inst.*, 555 U.S. 488, 493 (2009).

Peña doesn't face a real and immediate threat of repeated injury. He alleges that "[i]f the Penuma device and procedure were redesigned to be safe and effective for cosmetic penile enlargement, FDA-cleared for this use[13], and truthfully marketed, there is a ***possibility*** that [he] would purchase a Penuma device and procedure in the future." FAC ¶ 69 (emphasis added). This is insufficient. The mere possibility that Peña *might* buy the Penuma again someday is not enough. The "threatened injury must be *certainly impending* to constitute injury in fact, and … allegations of possible future injury are not sufficient." *Rahman v. Mott's LLP*, 2018 WL 4585024, at *2 (N.D. Cal. Sept. 25, 2018) (quoting *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013)) (emphasis added); *see Lanovaz v. Twinings N. Am., Inc.*, 726 F. App'x 590, 591 (9th Cir. 2018) (holding that plaintiff's statement that she would "consider buying" the products in the future did not support a finding of actual or imminent injury); *Sciacca v. Apple, Inc.*, 362 F. Supp. 3d 787, 803 (N.D. Cal. 2019) (dismissing injunctive relief claim because plaintiff "only alleges possible future injury," not an injury that is "certainly impending"); *Rodriguez*, 2021 WL 1985031, at *4-5 (same). In any event, FDA has officially cleared the Penuma for uses that expressly include cosmetic penile enlargement, so there is no threat of future injury to Peña—or to any member of the class he seeks to represent.

CONCLUSION

For all these reasons, the Court should dismiss Peña's First Amended Class Action Complaint.

/ / /

/ / /

[13] FDA expressly cleared the Penuma for this use earlier this year. RJN, Ex. B at 1-3.

Dated: August 1, 2022

Respectfully submitted,

SHOOK, HARDY & BACON L.L.P.

By: /s/ *Amir M. Nassihi*
Amir M. Nassihi
Michael L. Mallow
Jennifer M. Stevenson
Mayela C. Montenegro-Urch

Jennifer M. Stevenson (admitted *pro hac vice*)
jstevenson@shb.com
SHOOK, HARDY & BACON L.L.P.
2555 Grand Boulevard
Kansas City, Missouri 64108
Telephone: (816) 474-6550
Facsimile: (816) 421-5547

Attorneys for Defendants INTERNATIONAL MEDICAL DEVICES, INC., MENOVA INTERNATIONAL, INC., GESIVA MEDICAL, LLC, JAMES J. ELIST M.D., a Medical Corporation, and DR. JAMES ELIST